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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/310,638	05/12/99	SOREQ	H 2391.00096

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EXAMINER

CROUCH, D

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

10
06/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/310,638

Applicant(s)

SOREQ ET AL.

Examiner

Deborah Crouch

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14, 17-20 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 15-16, 21-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14, 17-20 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Applicant's arguments filed May 4, 2001 in paper no. 7 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-10,15,16, 21 and 22 stand withdrawn from further consideration. Claims 11-14, 17-20 and 23-25 are pending.

This application contains claims 1-10,15,16, 21 and 22 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The requirements set forth in 37 CFR 1.821(a)(1) and (a)(2) for sequence rule compliance have been met. However, applicants in filing the Sequence Listing, failed to request entry into the specification. In response to this office action, applicants should request entry of the Sequence Listing into the specification.

The terminal disclaimer filed on May 4, 2001 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 5,932,780 has been reviewed and is accepted. The obviousness type double patenting rejection has been overcome.

Applicants' amendments have overcome the rejection in the previous office action under 35 U.S.C. 101.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicants' arguments are persuasive for written description based on the present specification's disclosure of splice variants, and the teachings of Erlich of mutations of both AChE and BChE. Erlich discloses only one variant for AChE, an amino acid substitution at position 322 (Erlich, page 289, col. 1, parag. 1). For BChE, Erlich discloses several amino acid substitutions, point mutations, insertions and

deletions (Ehrlich, page 288, col. 2, parag. 1). Thus, claims 11-14, 17-20 and 23-25 meet written description.

Claims 11-14, 17-20 and 23-25 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic mice and frog tadpoles whose genomes comprise a transgene comprising a promoter operatively linked to a DNA sequence encoding a splice variant of human AChE expressing AChE with acetylcholine esterase activity, wherein said sequence is expressed in cells of said mouse and where said mouse or tadpole exhibits changes in its neuromuscular junction structure, and assay systems of said mouse or tadpole, does not provide enablement for the preparation and use of transgenic animals comprising any and all variants of said cholinesterase genes or assay systems of these animals for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments regarding promoters is persuasive and such has been implemented in the scope of enablement above.

Applicants argue that AChE is a secretory extracellular protein, and imply that the membrane structure is not needed for activity. Applicants also argue that a glycosylation is not needed for the esterase activity of AChE and that active protein has been produced in *E. coli*. Applicants argue that AChE has more than one use in that Dr. Soreq has filed other applications relating to neurite growth promotion and neuronal differentiation activity in progenitor cells. These arguments are not persuasive.

These arguments are not substantiated by declaration or publications, and without substantiation they are not persuasive. Further, regardless of the use of the produced AChE, it would need to be active in esterase activity, neurite growth promotion or neuronal differentiation activity. While the protein may have several activities, those activities need to be present in the produced protein. The predictability of the protein having this activity is the focus one part of the enablement rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11,29,23 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 (d) lacks antecedent basis for "said synthetic variants."

Claim 19 contains two mentions of "variants of AChE."

Claim 23 is confusing as it is apparently missing reference to what the mammal contains.

Claim 25 is confusing as there is no SEQ ID NO: 28 disclosed.

The claims are free of the prior art. At the time of the instant invention the art did not teach or suggest the production of transgenic mice or *Xenopus* whose genome contained and expressed a DNA sequence encoding any human AChE or human BChE.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126. The examiner's SPE is Karen Hauda, whose telephone number is (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Art Unit Patent Analyst, Kay Pickney, whose telephone number is (703) 305-3553.

The fax number is (703) 308-4242.

Dr. D. Crouch
June 27, 2001

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